Filing Date: April 29, 1998

Title: PHARMACEUTICAL CARRIER DEVICE SUITABLE FOR DELIVERY OF PHARMACEUTICAL COMPOUNDS TO MUCOSAL

SURFACES WD:601393

REMARKS

This responds to the Office Action mailed June 01, 2005.

No claims are amended, added, or newly canceled; as a result, claims 1-3, 5-10, 12, 13, 15-18, 33 and 34 are pending in this application.

Obviousness-type Double Patenting Rejection

Claims 1-3, 5-10, 12, 13, 15-18, 33, and 34 were rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claim 1 of US Patent 5,800,832 and over claims 1-27 of US Patent 6,159,498. This rejection is respectfully traversed.

The Examiner asserted that, "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the scope of the patented claims with respect to polymers in the first layer." Office Action at page 2.

The claims of the cited documents are drawn to a water-soluble pharmaceutical carrier device, whereas the present invention is drawn to a water-erodible pharmaceutical carrier device, a water-erodible layered film disk, and a water-erodible layered flexible film. Applicants submit that the present invention does not encompass the claims of the cited patents and is patentably distinct from the claims of the cited patents.

It is axiomatic that during examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. MPEP § 2173.05(a). Applicants' specification discloses at page 9 that the present invention is made of water-erodible components. However, in contrast, the two cited documents disclose at column 4 that the inventions therein are made of water-soluble components. Based on Applicants' disclosure, the broadest reasonable interpretation of Applicants' claims would not include a water-soluble pharmaceutical carrier device, a water-soluble layered film disk, and a water-soluble layered flexible film. An analogy is rocks being pelted with ocean waves. The rocks erode slowly with time, but they cannot be considered to be soluble in the ocean water.

Withdrawal of this rejection is respectfully requested.

Filing Date: April 29, 1998

Title: PHARMACEUTICAL CARRIER DEVICE SUITABLE FOR DELIVERY OF PHARMACEUTICAL COMPOUNDS TO MUCOSAL

SURFACES WD:601393

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 3 was rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. This rejection is respectfully traversed.

The Examiner considered the terms *polysaccharides* and *polyaminoacids* vague because it is unclear to him if those polymers are water-soluble. Further, the Examiner considered the terms *collagen* and *chitin* "indefinite in the context of the claimed water-erodible character of the first layer because most types of collagen are insoluble in water and chitin is practically insoluble in water." Office Action at page 2.

It is axiomatic that definiteness of claim language is not analyzed in a vacuum, but rather in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP § 2173.02. As Applicants have pointed out in the above obviousness-type double patenting rejection, Applicants' specification discloses at page 9 that the present invention is made of water-erodible components, and water-erodible components would not be considered water-soluble. Therefore, it is perfectly reasonable for the claims to recite materials which are not water-soluble.

The Examiner's apparent position that the materials in claim 3 be water-soluble is improper because it is inconsistent with Applicants' disclosure. Accordingly, based on Applicants' disclosure, claim 3 is not indefinite for including materials which are not water-soluble.

Withdrawal of this rejection is respectfully requested.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 09/069,703 Filing Date: April 29, 1998 Dkt: 1195.335US1

Title: PHARMACEUTICAL CARRIER DEVICE SUITABLE FOR DELIVERY OF PHARMACEUTICAL COMPOUNDS TO MUCOSAL

SURFACES WD:601393

Conclusion

Applicants respectfully request reconsideration of their claims in view of these remarks and withdrawal of the rejections. Applicants respectfully solicit allowance of their claims and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

GILLES H TAPOLSKY ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. Box 2938

Minneapolis, MN 55402

(612) 373-6939

Date 1, 2005

A. James Nelson

Reg. No. 28,650

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this ______ day of September, 2005.

CANDIS BUENDING

Name

Signature